

REMARKS

Rejection under 35 U.S.C. § 112, First Paragraph – Written Description

The Examiner rejected claims 1, 4-12, 14, and 16-20 under 35 U.S.C. 112, First Paragraph, as failing to comply with the written description requirement. Specifically, the Examiner asserted that "claims require that the distal and proximal most ends of the first stent are coincident with the distal and proximal most ends of the graft, but this is never recited in the specification" (page 2, last paragraph, Office action dated June 22, 2007).

Applicants respectfully disagree. At the outset, Applicants point out that, according to MPEP 2163, "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, **figures**, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the **disclosure of drawings** or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991)." (emphases added)

Claims 1, 2, 6, 9-11, 14, 17, 18, and 20 are generally directed to stent tissue graft prostheses that include a first expandable stent, either a tissue graft (claims 1, 2, 6, 9-11, 14, 17, and 18) or a multilayered tissue graft construct (claim 20), and a tubular member, where the tubular member is disposed over the tissue graft or construct and around the first stent and retaining the tissue graft disposed on the first stent. A most distal end of a first distal stent end is *at least coincident* with either a most distal end of a distal tissue graft end (claims 1, 2, 6, 9-11, 14, 17, and 18) or a most distal end of the

distal construct end (claim 20). A most proximal end of a first proximal stent end is *at least coincident* with either a most proximal end of a proximal tissue graft end (claims 1, 2, 6, 9-11, 14, 17, and 18) or a most proximal end of the proximal construct end (claim 20). This is to prevent the tissue graft or multilayered construct from everting or folding into a passage of the first expandable stent.

Applicants satisfied the written description requirement because the drawings, such as, *e.g.*, Figures 1 and 2, demonstrate possession of stent tissue graft prostheses where *the most distal and most proximal ends of the first stent graft 21 are at least coincident with the most distal and most proximal ends of the tissue graft 24 or the multilayered construct*. Applicants point out that the "wherein" clauses in independent claims 1 and 20 include the term "at least coincident" (rather than just "coincident"). The term "at least" is a commonly used term and is defined by the Merriam-Webster's Collegiate Dictionary to mean "at the minimum" (Merriam-Webster's Collegiate Dictionary, Tenth Edition, Merriam-Webster, Incorporated, Springfield, Massachusetts, U.S.A., 1999, page 663; Appendix A). It is clearly shown in Figures 1 and 2 that the most distal and most proximal ends of the first stent are at the minimum coincident (*i.e.*, coincident or longer) with the most distal and most proximal ends of the tissue graft or multilayered construct because of the extensions 66. Therefore, Figures 1 and 2 provide support for stent tissue graft prosthesis where the most distal and most proximal ends of the first stent graft 21 are at least coincident with the most distal and proximal ends of the tissue graft 24 or the multilayered construct

Given the above, Applicants respectfully request the written description rejection of claims 1, 4-12, 14, and 16-20 be withdrawn.

Rejection under 35 U.S.C § 103 – Obviousness

Summary

The Examiner also issued a 35 U.S.C § 103(a) rejection of claims 1, 6, 9-11, 14, 17, 18 and 20 as being unpatentable over U.S. Pat. No. 5,865,723 to Love (Love) in view of U.S. Pat. No. 5,571,173 to Parodi (Parodi); rejection of claims 4, 5, 7 and 8 as

being unpatentable over Love in view of Parodi and further in view of U.S. Pat. No. 6,358,284 B1 to Fearnot *et al* (Fearnot *et al.*); and rejection of claims 1, 12 and 16 as being unpatentable over U.S. Pat. No. 5,628,788 to Pinchuk (Pinchuk) in view of Parodi and Fearnot *et al.*

Applicants disagree with the Examiner's rejections for reasons described below.

Claims 1, 2, 6, 9-11, 14, 17 and 18 are directed to stent tissue graft prostheses that include: i) a first expandable stent having a first distal stent end and a first proximal stent end, a tubular wall and a passage extending longitudinally therethrough; ii) a tissue graft having a distal tissue graft end and a proximal tissue graft end and disposed on said first stent; and iii) a tubular member having a wall and a passage extending longitudinally therethrough, said tubular member being disposed over said tissue graft and around said first stent and retaining said tissue graft disposed on said first stent. *A most distal end of the first distal stent end is at least coincident with a most distal end of the distal tissue graft end and a most proximal end of the first proximal stent end is at least coincident with a most proximal end of the proximal tissue graft end to prevent the tissue graft from everting or folding into the passage of the first expandable stent.*

The independent claim 20 is directed to a stent tissue graft prosthesis that includes: i) a first expandable stent having a first distal stent end and a first proximal stent end, a tubular wall and a passage extending longitudinally therethrough; ii) a multilayered tissue graft construct having a distal construct end and a proximal construct end, a tubular wall and a passage extending longitudinally therethrough and disposed on said first stent; and iii) a second expandable stent having a tubular wall and a passage extending longitudinally therethrough, said second stent being disposed over and around said construct and said first stent, and retaining said construct disposed on said first stent. *A most distal end of the first distal stent end is at least coincident with a most distal end of the distal construct end and a most proximal end of the first proximal stent end is at least coincident with a most proximal end of the proximal construct end to prevent the multilayered tissue graft from everting or folding into the passage of the first expandable stent.*

Argument for Claims 1, 6, 9-11, 14, 17, 18 and 20

The Examiner rejected claims 1, 6, 9-11, 14, 17, 18 and 20 as being unpatentable over Love in view of Parodi. The Examiner stated that although "Love does not disclose that the distal and proximal most portions of the first stent are coincident with the distal and proximal ends of the graft" (Office Action dated June 22, 2007, page 3, last paragraph), because it is well known in the art of stent grafts to make stents and graft ends coincident, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the prosthesis of Love have the stent and graft ends be coincident, as taught by the Parodi reference.

At page 11, lines 10-19 of the instant specification, Applicants teach that the distal and proximal ends of tissue graft need to be coincident with the ends of the inner stent to prevent the tissue graft from folding over or inverting into passage of the inner stent during pulsatile flow of blood when the prosthesis is positioned in a blood vessel. The fold-over or eversion, as further taught by the Applicants, can cause turbulent blood flow and can clearly create lumen restriction for thrombus to build up on and further restrict the blood flow (Specification, at page 11, lines 10-19).

Contrary to the Examiner's assertion, it would not have been obvious to combine the Love and Parodi references to arrive at the prosthesis of the present invention because Love **teaches away from** Applicants' invention. For example, at column 6, lines 40-46, Love teaches specifically that:

"... The rolled tissue supported by the frame will often **extend slightly beyond** the ends of the frame (...). Such **tissue extensions** can facilitate suturing of the prosthesis to form end-to-end and end-to-side anastomoses in performing [coronary artery bypass graft] CABG and other procedures." (emphases added)

Also, several figures, e.g., Figures 6-9 of the Love reference, clearly illustrate the tissue extending beyond the ends of the inner stent. Because Love clearly teaches that tissue should extend beyond the inner stent/frame to facilitate suturing, one would be dissuaded to alter the prosthesis of Love to make the ends of the stent and graft coincident, as taught by Parodi.

In the recent *KSR* case the Supreme Court stated that it is "...important to **identify a reason** that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex, Inc.*, 82USPQ2d 1385, 1389 (2007) (emphasis added) In this instance, one would not have a reason to combine the Love and Parodi references to arrive at the Applicants' invention because folding-over or eversion of tissue into the passageway of the inner stent upon implantation into a blood vessel is never identified as a potential problem associated with the device of Love. In fact, Love specifically teaches that it is preferred to have the ends of the tissue extend beyond the ends of the frame (i.e., inner stent) to facilitate suturing to form end-to-end and end-to-side anastomoses during surgical procedures (Love, column 6, lines 40-46). Thus, one would not have a reason to modify the device of Love by applying teachings of Parodi.

Clearly, Applicants' invention of claims 1, 6, 9-11, 14, 17, 18 and 20 would not have been obvious in view of the Love and Parodi references. Consequently, Applicants request that the 35 U.S.C § 103(a) rejection of claims 1, 6, 9-11, 14, 17, 18 and 20 as being unpatentable over Love in view of Parodi be withdrawn.

Argument for Claims 4, 5, 7 and 8

The Examiner rejected claims 4, 5, 7 and 8 as being unpatentable over Love in view of Parodi and further in view of Fearnot *et al.*

As discussed above, because the Love reference teaches away from the invention of claim 1 and because one of ordinary skill in the art would not have a reason to modify the prosthesis of Love to have the stent and graft ends coincide, as taught by Parodi, the invention of independent claim 1 would not have been obvious.

Furthermore, the Fearnot *et al.* reference does not provide a reason to modify the prosthesis of Love to include an inner stent with the most proximal and most distal ends being are at least coincident with the most proximal and most distal graft eds, respectively, as taught by Parodi.

Because the stent tissue graft prosthesis of Applicants' claims 1 is both novel and non-obvious, the prostheses defined by the claims depending on claim 1, are also novel and non-obvious. In particular, claims 4, 5, 7 and 8 are not obvious under 35

U.S.C. §103 over Love in view of Parodi and further in view of Fearnot *et al.* Applicants request that the obviousness rejection of claims 4, 5, 7 and 8 be withdrawn.

Argument for Claims 1, 12 and 16

The Examiner also rejected claims 1, 12 and 16 as being unpatentable over Pinchuk in view of Parodi and further in view of Fearnot *et al.* The Examiner stated that although the Pinchuk 1) does not teach grafts comprising multiple layers of tissue, and 2) does not teach proximal and distal stent ends being coincident with the proximal and distal graft ends, respectively, Fearnot *et al.* discloses the use of tubular grafts comprising layers of submucosa tissue and Parodi discloses a prosthesis having stent and graft ends coincident. The Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the submucosa tissue graft layers as taught by Fearnot *et al.* and extend the stent lengths allowing them to be coincident as taught by Parodi with the double layered stent graft of Pinchuk.

As mentioned above, in the recent *KSR* case the Supreme Court stated that it is "...important to **identify a reason** that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR at*, 1389 (emphasis added). In this instance, one would not have a reason to combine the Pinchuk and Parodi references to arrive at the Applicants' invention because neither the Pinchuk or the Parodi reference provides a reason that would lead one to believe that there was a problem with the design of the prosthesis of Pinchuk and having ends of the inner stent to be coincident with or longer than the tissue graft, as taught by Parodi, would solve the problem.

Also, based on the two primary references (Love and Pinchuk) provided by the Examiner, it appears that, generally, the prior art did not appreciate the advantages of having the ends of the inner stent at least coincide with the ends of the graft material in a device that includes graft material between, for example, two stents. Indeed, the invention of independent claim 1 is that the device has the inner stent ends coincide with or are longer than the graft ends so that the tissue graft would not evert or fold into the passage.

Next, the Fearnot *et al.* reference does not provide a reason to modify the prosthesis of Pinchuk to include an inner stent with the most proximal and most distal ends being are at least coincident with the most proximal and most distal graft eds, respectively, as taught by Parodi.

In view of the above remarks, it would not have been obvious to one of skill in the art to combine the Pinchuk, Parodi, and Fearnot *et al.* references to arrive at the invention of claim 1. Because the stent tissue graft prosthesis of Applicants' claims 1 is both novel and non-obvious, the prostheses defined by the claims depending on claim 1, are also novel and non-obvious. In particular, claims 12 and 16 are not obvious under 35 U.S.C. §103 over Pinchuk in view of Parodi and further in view of Fearnot *et al.* Accordingly, Applicants request that the obviousness rejection of claims 1, 12 and 16 be withdrawn.

New Claims 21 and 22

New claims 21 and 22 are added to further distinguish Applicants' invention from the cited references in that the ends of inner stent of the prosthesis extend beyond the respective ends of the tissue graft (claim 21) or the respective ends of the multilayered tissue graft construct (claim 22) so as to advantageously prevent any eversion or folding of the tissue graft or multilayered tissue graft construct into the passage of the prosthesis.

SUMMARY

Applicants respectfully submit that the present application is now in condition for allowance. If, for any reason, the Examiner feels a discussion would expedite the prosecution of this application, the Examiner is kindly invited to contact the undersigned at (312) 245-5398.

Respectfully submitted,

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Appendix A

